

DATE OUT: 06/18/2012

SUBJECT: PRODUCT CHEMISTRY REVIEW OF: TGAI[ ]; MUP [ ]; EUP [X]  
BARCODE NO.: 401224 REG./FILE SYMBOL NO.: 60061-128  
PRODUCT NAME: ValvTect Marine Premium Diesel Additive with BioGuard Microbiocide  
MRID NO: 429385-03, 473676-01,-02,-03  
COMPANY NAME: Kop-Coat, Inc ACTION CODE: 676

FROM: Boris Yurchak, Chemist  
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**INTRODUCTION:**

A Reregistration Eligibility Decision (RED), Case No. 3028, was issued on 09/2007 for the Active Ingredient Bioban P-1487. According to the RED, the generic database supporting the reregistration of Bioban P-1487 for currently registered uses has been reviewed and found to be substantially complete.

In the 8-month response to the Bioban P-1487 RED, the Kop-Coat, Inc, provided EPA Form 8570-35 (Data Matrix), dated 03/28/2012; EPA Form 8570-4 (Confidential Statement of Formula), a basic formulation, dated 01/01/201; a draft label, punch date 01/24/2012; and MRID Nos. 429385-03, 473676-01,-02,-03. The registrant is requesting reregistration of the product ValvTect Marine Premium Diesel Additive with BioGuard Microbiocide, EPA Reg. No. **60061-128**.

**FINDINGS:**

1. EPA Reg. No. **60061-128** is an end-use product containing the active ingredient [REDACTED]. A label claim nominal concentration is provided for its two components: 4-(2-Nitrobutyl) **Morpholine** (21.8%) and 4,4-(2-Ethyl-2-nitrotrimethylene) **Dimorpholine** (1.35%), and other inert ingredients content of 76.85%. The product is a pesticide to prevent bacterial growth in diesel fuel. The product is produced by a non-integrated system.
2. The CSF for the basic formulation is not acceptable as presented because the trade name of [REDACTED] is not matched with [REDACTED] provided in column No. 10. The CAS Number relates to [REDACTED]. The trade name pertains to [REDACTED]. The registrant is requested to harmonize this issue. Other information is acceptable. The nominal concentration of the components of the active ingredient agrees with that on the label and meets the requirements of PR Notice 91-2. The certified limits for the active and inert ingredients are acceptable in accordance with 40 CFR §158.350 (b)(2).

Note 1: [REDACTED]

Note 2: [REDACTED]

Note 3: [REDACTED]

3. Data provided in MRID 473676-01 concerning the Product Identity and Composition do not support the CSF data. The formulation of the product provided in said MRID does not show the components of A.I. (Morpholine and Dimorpholine). Solvent is represented with different substances [REDACTED]. The nominal concentrations of A.I. source, Detergent and Solvent do not coincide with the same on the CSF. Therefore, the data do not satisfy the requirements of the Guideline 830.1550.
4. Data provided in MRID 473676-01 concerning the Description of the Materials Used to Produce the Product do not coincide with the CSF data. The formulation of the product provided in said MRID contains a solvent that differs from the same on the CSF. Solvent [REDACTED] listed in the MRID is a mixture which contains [REDACTED]. Solvent included in the CSF is represented by a single substance [REDACTED]. There is no justification that these products are identical or similar, at least. Therefore, the data do not satisfy the requirements of the Guideline 830.1600.
5. The data concerning the Oxidation/Reduction Chemical Incompatibility, Explodability, Miscibility, and Dielectric Breakdown Voltage have not been found in the MRIDs provided for the product. Therefore, the requirements of the Guideline 830.6314,-6316,-6319,-6321 are not satisfied.
6. Data reported in MRID Nos. 473676-03 concerning the Storage Stability and Corrosion Characteristics cannot be accepted due to the following:
  - a. The test was conducted only for one component of A.I. (Morpholine).
  - b. Average initial Morpholine content was observed of 17.4% which differ from the nominal concentration of the same component in the subject product 21.8% shown on the CSF and on the label.
  - c. The test data for 3, 6, 9, and 12 months storage were scheduled to be reported upon completion and are not available yet.

The test was conducted for product ValTest Marine Premium with Biogard Additive that is not the subject product. Due to the above, the requirements of the Guideline 830.6317 and 830.6320 are not satisfied.

7. Except for Finding Nos. 3-6, the data reported in MRIDs Nos. 429385-03, 473676-01,-02,-03 satisfy the product data requirements under Subgroups A and B, which pertain to Description of the Materials Used to Produce the Product, Discussion of Formation of Impurities, Enforcement Analytical Method, and Physical and Chemical Properties, respectively.
- 8a. The Ingredients Statement on the draft label should be revised to read OTHER ingredients instead of INERT ingredients as per PR Notices 97-6.
- 8b. The Storage and Disposal Statements are acceptable in accordance with 40 CFR §156.10(i)(2)(ix) and PR Notice 83-3 with a comment: the subheading Container Disposal should be changed to Container Handling.

8c. The Physical or Chemical Hazards Statement on the draft label is acceptable.

NOTE TO CRM: The labeling issues should be addressed during label review.

**CONCLUSIONS:**

After submission of a revised CSF (Finding No. 2) and data, as noted in Finding Nos. 3 - 6, the registrant will satisfy the product chemistry requirements for the reregistration of EPA Reg. No. 60061-128.

**Product Chemistry Data**

**Subgroup A: Series 830.1550 - 830.1800 (40 CFR 158.310 (e), 40 CFR 158.320 - 158.355)**

<b>GUIDELINE REFERENCE NO. (GRN)/ TITLE 830</b>	<b>40 CFR §</b>	<b>MRID Number</b>	<b>Data Fulfilled</b>
.1550 Product Identity and Composition	158.320	473676-01 CSF	N (see Finding No. 3)
.1600 Description of the Materials Used to Produce the Product	158.325	471739-01 CSF	N (see Finding No. 4)
.1620 Description of Production Process	158.330	[Not required for products produced by a non-integrated system]	NR
.1650 Description of the Formulation Process	158.335	471739-01	Y
.1670 Discussion of Formation of Impurities	158.340	471739-01	Y
.1700 Preliminary Analysis	158.345	[Not required for products produced by a non-integrated system]	NR
.1750 Certified Limits	158.350	CSF	Y
.1800 Enforcement Analytical Method	158.355	429385-03	Y

**Subgroup B: Series 830.6302 - 7950 (40 CFR 158.310(e))**

<b>Guideline Reference No. (GRN) / Title 830</b>	<b>Value or Qualitative Description</b>	<b>MRID Number</b>	<b>Data Fulfilled</b>
.6302 Color	Yellow @ 22°C	473676-02	Y
.6303 Physical State	Liquid @ 22°C	473676-02	Y
.6304 Odor	Characteristics of petroleum products	473676-02	Y
.6313 Stability	Not applicable for EUP		NR
.6314 Oxidation/Reduction Chemical Incompatibility			N (see Finding No.5)
.6315 Flammability/ Flame Extension	Flash point=48.0°C (118°F)	473676-02 CSF	Y



.6316 Explodability			N (see Finding No.5)
.6317 Storage Stability		473676-03	N (see Finding No. 6)
.6319 Miscibility			N (see Finding No.5)
.6320 Corrosion Characteristics		473676-03	N (see Finding No. 6)
.6321 Dielectric Breakdown Voltage			N (see Finding No.5)
.7000 pH	9.05 at 25 <sup>0</sup> C	473676-02 CSF	Y
.7050 UV/ Visible Light Absorption	Not applicable for EUP		NR
.7100 Viscosity	3.590 mm <sup>2</sup> /s (cSt)	473676-02	Y
.7200 Melting Point	Not applicable for EUP		NR
.7220 Boiling Point	Not applicable for EUP		NR
.7300 Density/ Bulk Density	RD=0.9590 (7.995 lb/gal)	473676-02	Y
	7.987 lb/gal	CSF	

Explanations: Y = Requirement fulfilled; N = Requirement not fulfilled; N/A = Not applicable; G = Data gap; U = Upgradeable; I = Incomplete or in progress; W = Waived

#### 830-1800 Enforcement of Analytical Method (MRID Nos. 429385-03)

The MRID Nos. 429385-03 identifies method to be a Gas Chromatography (GC) for the active ingredient Bioban-P-1487. The method provides procedure for preparing samples and a description of the instrument system. The GC system consists of the following:

#### **Instrumentation:**

Gas Chromatograph: Spectra-Physics SP7100 or Hewlett Packard 5890A with integrating computer  
Column: DB-5MS 5, 30m x 0.25mm x 0.25 µm  
Detector: Flame Ionization (FID)

#### **Chromatographic Conditions:**

Detector temperature: 250<sup>0</sup>C  
Carrier Gas: Helium  
Column temperature: 325<sup>0</sup>C  
Sample size: 1.0 µL

The method is adequate for determination of active ingredient Bioban P-1487 including its two components Morpholine and Dimorpholine with a remark: supportive chromatograms are not provided. Nevertheless, the data are acceptable since the retention times and the Response Factors for both components are listed. The requirements of Guideline 830.1800 are satisfied.